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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/082,247

05/20/1998

JAMES G. NADEAU

P-2821RI

2478

7590

06/12/2006

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EXAMINER

TUNG, JOYCE

ART UNIT

PAPER NUMBER

1637

DATE MAILED: 06/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/082,247

Applicant(s)

NADEAU ET AL.

Examiner

Joyce Tung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 April 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-42 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 4/26/05.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

The applicant's response filed 4/26/05 to the Office action mailed 10/26/04 has been entered. Claims 1-42 are pending.

1. The request of the original patent in section 1 of the Office action mailed 10/26/04 is withdrawn based upon the argument.
2. The request for citing each reference from the original patent on the PTO-1449 of the instant patent in section 5 of the Office action mailed 10/26/04 is withdrawn because the PTO-1449 with cited references from the original patent is filed April 26, 2005.
3. The rejection of claims 21-42 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn because of the amendment.
4. The request for the record establishing the ownership interest in section 2 of the Office action mailed 10/26/04 is maintained because the record was not submitted.

The assignee has not established its ownership interest in the application. There is no submission in the record establishing the ownership interest by either (a) providing documentary evidence of a chain of title from the original inventor(s) to the assignee, or (b) specifying (by reel and frame number) where such documentary evidence is recorded in the Office (37 CFR 3.73(b)). There is no 3.73(b) document.

5. In accordance with 37 CFR 1.175(b)(1), a supplemental reissue oath/declaration under 37 CFR 1.175(b)(1) must be received before this reissue application can be allowed.

Claims 1-42 remain rejected as being based upon a defective reissue declaration under 35 U.S.C. 251. See 37 CFR 1.175. The nature of the defect is set forth above.

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Receipt of an appropriate supplemental oath/declaration under 37 CFR 1.175(b)(1) will overcome this rejection under 35 U.S.C. 251. An example of acceptable language to be used in the supplemental oath/declaration is as follows:

"Every error in the patent which was corrected in the present reissue application, and is not covered by a prior oath/declaration submitted in this application, arose without any deceptive intention on the part of the applicant."

6. Applicant is notified that any subsequent amendment to the specification and/or claims must comply with 37 CFR 1.173(b).

The amendment filed September 20, 2004 proposes amendments to claims 21-42 that do not comply with 37 CFR 1.173(b), which sets forth the manner of making amendments in reissue applications. A supplemental paper correctly amending the reissue application is required.

37 CFR 1.173. Reissue specification, drawings, and amendments.

The amendment must be made pursuant to 37 CFR 1.173(b) which states that "(b) Making amendments in a reissue application. An amendment in a reissue application is made either by physically incorporating the changes into the specification when the application is filed, or by a separate amendment paper. If amendment is made by incorporation, markings pursuant to paragraph (d) of this section must be used. If amendment is made by an amendment paper, the paper must direct that specified changes be made, as follows:

(2) Claims. An amendment paper must include the entire text of each claim being changed by such amendment paper and of each claim being added by such amendment paper. For any claim changed by the amendment paper, a parenthetical expression "amended," "twice amended," etc., should follow the claim number. Each changed patent claim and each added claim must include markings pursuant to paragraph (d) of this section, except that a patent claim or added claim should be canceled by a statement canceling the claim without presentation of the text of the claim."

1.173(d) states "(d) Changes shown by markings . Any changes relative to the patent being reissued which are made to the specification, including the claims, upon filing, or by an amendment paper in the reissue application, must include the following markings:

- (1) The matter to be omitted by reissue must be enclosed in brackets; and
- (2) The matter to be added by reissue must be underlined, except for amendments submitted on compact discs (§§ 1.96 and 1.821(c)). Matter

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added by reissue on compact discs must be preceded with "<U>" and end with "</U>" to properly identify the material being added."

7. The response indicates that a Supplemental Declaration under 37 CFR 1.175(b) was submitted on April 26, 2005. However, there is a substitute declaration under 37 CFR 1.175(b) filed April 26, 2005. It is unclear whether or not the substitute declaration under 37 CFR 1.175(b) filed April 26, 2005 is the Supplemental Declaration under 37 CFR 1.175(b). However, the substitute declaration under 37 CFR 1.175(b) filed April 26, 2005 was not properly filed (See MPEP 1414.01). Thus, the rejection is maintained.

Allowable Subject Matter

8. Claims 1-42 are free of prior art, but rejected for other reasons.

9. The following is a statement of reasons for the indication of allowable subject matter:

Concerning claims 1-42, no prior art has been found teaching or suggesting a method of concurrently generating a secondary amplification product and an amplification product in a primer based nucleic acid amplification comprising: hybridizing a signal primer to a target sequence and a first amplification primer to the target sequence upstream of the signal primer, wherein a characteristic of the signal primer is that it may not function as an amplification primer; extending the hybridized signal primer on the target sequence to produce a signal primer extension product and extending the hybridized first amplification primer on the target sequence such that the extension of the first amplification primer displaces the signal primer extension product from the target sequence; hybridizing a second amplification primer to the signal primer extension product and extending the hybridized second amplification primer on the signal primer extension product to produce a second amplification product comprising a newly synthesized strand; displace the newly synthesized strand from the signal primer extension product and

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hybridizing the signal primer to the displaced newly synthesized strand and extending the signal primer in which a double stranded secondary amplification product is generated.

Summary

10. No claims are allowable.

11. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joyce Tung whose telephone number is (571) 272-0790. The examiner can normally be reached on Monday - Friday, 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Joyce Tung *J. T*
May 31, 2006

Kenneth R. Horlick
KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
6/8/06